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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,251	04/05/2007	Fabrizio Dolfi	290485US0X PCT	2049
22850	7590	09/29/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER HUANG, GIGI GEORGIANA	
			ART UNIT	PAPER NUMBER
			1612	
			NOTIFICATION DATE	DELIVERY MODE
			09/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/580,251	DOLFI ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/12/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in the reply filed on May 26, 2009 is acknowledged. The traversal is on the grounds that there is no burden and that the burden of a lack of unity has not been met. This is not found persuasive because the instant case is submitted under 35 U.S.C. 371, the Unity of Invention practice in MPEP §1850 and MPEP §1893.03(d) was followed, not restriction practice. Thus the criteria for burden stated in MPEP §803 for national applications filed under 35 U.S.C. 111(a) does not apply (MPEP §801). The lack of unity has been addressed in the previous action. As the technical feature did not contribute over the art, the restriction was applied appropriately. In regards to Applicant's assertion that lack of unity has not been met, this is not persuasive as the technical feature linking the claims is a composition comprising idrocilamide wherein Bayysat et al. taught a composition comprising idrocilamide (see previous action). Therefore the technical feature linking the claims does not constitute a special technical feature as it lacks novelty and the claims are restricted.

The requirement is still deemed proper and is therefore made FINAL.

Status of Application

2. Applicant has elected Group II in response to restriction requirement and for the examination.

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Due to restriction, based on election of Group II, claims 1-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 17-31 have been added by amendment.

Claims 16-31 are present for examination at this time.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims recite the term "cosmetic active agent" wherein there is no description as to what materials would constitute a "cosmetic active agent". There are also no structural identifying characteristics for the compounds. Therefore, the claimed invention is not supported by adequate written description.

4. Claims 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the term "skin calmative and

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protective agents" wherein there is no description as to what materials would constitute a "skin calmative and protective agents ", it excludes sunscreens which are recited separately. There are also no structural identifying characteristics for the compounds. Therefore, the claimed invention is not supported by adequate written description.

5. Claims 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims recite the term "pro-penetrating agents" wherein there is no description as to what materials would constitute a "pro-penetrating agents ". There are also no structural identifying characteristics for the compounds. Therefore, the claimed invention is not supported by adequate written description.

6. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claim recites the inclusion of an "immunosuppressant product". The claim covers all compounds having these characteristics or properties, but there is no evidence that there is any per se structure/function relationship or structural identifying characteristics disclosed for the group. In fact, the claims are directed to what the compound does, but not what it is

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wherein addresses compounds not yet discovered that are not in Applicant's possession as addressed by the screening process of Shaw et al. (U.S. Pat. Pub. 2009/0221568, Abstract) which is submitted after Applicant's date of filing. Therefore, the claimed invention is not supported by adequate written description.

7. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claim recites the inclusion of an "antiproliferative agent". The claim covers all compounds having these characteristics or properties, but there is no evidence that there is any per se structure/function relationship or structural identifying characteristics disclosed for the group. In fact, the claims are directed to what the compound does, but not what it is wherein addresses compounds not yet discovered that are not in Applicant's possession as addressed by the screening process of Shaw et al. (U.S. Pat. Pub. 2009/0221568, Abstract, anti-neoplastic is also anti-proliferative) and Wood et al. (U.S. Pat. Pub. 2009/0215805, paragraph 85) which is submitted after Applicant's date of filing. Therefore, the claimed invention is not supported by adequate written description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 25 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the term "cosmetic active agent" wherein it is unclear what materials would constitute a "cosmetic active agent", it does not allow one of skill in the art to ascertain the metes and bounds.

9. Claims 25 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the term "skin calmative and protective agents" wherein it is unclear what materials would constitute a "skin calmative and protective agents". The term is confusing and it excludes sunscreens which are recited separately. It does not allow one of skill in the art to ascertain the metes and bounds.

10. Claims 25 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the term "pro-penetrating agents" wherein it is unclear what materials would constitute "pro-penetrating agents", it does not allow one of skill in the art to ascertain the metes and bounds.

11. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the phrase "obtained by dispersing a fatty phase in an aqueous phase (O/W) or, conversely, (W/O)" wherein it is unclear what it is referring to as a pharmaceutical form. It appears to be a reference to the emulsion as a

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product by process but it is unclear what it is actually addressing. It does not allow one of skill in the art to ascertain the metes and bounds.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 16-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arkin et al. (WO 02/074290) in view of Bannwarth et al. (Tissue and systemic diffusion of idrocilamide after cutaneous administration).

The translation of Bannwarth is included and all references are to the translation.

Arkin et al. teaches a method of treating rosacea, a chronic inflammatory disorder, by topically administering a composition comprising a nonsteroidal anti-inflammatory drug. The composition can be a single nonsteroidal anti-inflammatory or a combination of them. The composition can be in conjunction with other conventional rosacea-treating agents preferably with metronidazole. See Examples 2, 4, 5 for the amounts of the nonsteroidal and the additives of the instant claims. Patients in the different stages of rosacea aged 21-70 were treated with improvement (see Page 4, 9-15).

Arkin does not expressly teach the inclusion of idrocilamide.

Bannwarth et al. teaches the anti-inflammatory properties of idrocilamide are known and that its topical application was effective. There was a reduction in the pain intensity and concentration of idrocilamide in the area. Bannwarth also teaches that the concentrations are similar when done with a diclofenac gel which is also a functionally equivalent nonsteroidal. Bannwarth also teaches that the physicochemical characteristics of idrocilamide as favors its passage through the epidermis (Abstract, Page 2-3, Results Page 4-6, Discussion Page 6-8).

It would have been obvious to one of skill in the art at the time of the invention to include idrocilamide in the invention of Arkin, as motivated by Bannwarth, as Bannwarth teaches that idrocilamide is an effective topical NSAID and the general teaching of Arkin is for the topical use of NSAIDS for rosacea. It also would have been obvious to substitute the idrocilamide for the diclofenac in the examples of Arkin as Bannwarth teaches the NSAIDS to be functionally equivalent. It is desirable for manufacturers to have analogous choices to substitute a functionally equivalent NSAID for another when motivated by pricing and availability and topical penetration of the NSAID used to produce the final product, and the physicochemical characteristics of idrocilamide as shown by Bannwarth favors its passage through the epidermis. The skilled artisan would have had a reasonable expectation of successfully treating rosacea by topically applying the composition comprising the NSAID.

Double Patenting

13. Claim 30 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19-29 of copending Application No.

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10590031. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim meets the broader copending claims and the copending claims 26-28 are optimization of the amount of metronidazole which is obvious for one of skill in the art to attain a therapeutic range with the least amount of side effects.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

14. Claims 16-31 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612